



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

GC America, Inc.
Mark Heiss, DDS
Director, Regulatory Affairs & Academic Affairs, and Professional Relations
3737 West 127th Street
Alsip, IL 60803

Re: K141562
Trade/Device Name: MSN-006
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Codes: EBG
Dated: June 23, 2014
Received: June 25, 2014

Dear Dr. Heiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

Indications for Use

510(k) Number (if known): K141562

Device Name: MSN-006

Indications for Use:

1. Fabrication of temporary crowns, bridges, inlays, onlays and veneers
2. Fabrication of long-term temporary restorations

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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1. Submitter Information:

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Date Prepared: June 10, 2014

2. Device Name:

Proprietary Name: MSN-006
Classification Name: Crown and Bridge, Temporary, Resin
Device Classification: Class II, 872.3770
Product Code: EBG

3. Predicate Devices:

Company	Device	510(k) No.	Date Cleared
3M ESPE AG DENTAL PRODUCTS	Protemp Plus	K073296	01/09/2008
DMG USA, INC	Luxatemp Ultra	K101710	09/28/2010
GC America Inc.	GC KALORE	K082434	11/14/2008
GC America Inc.	G-Cem Automix	K073283	02/20/2008
GC America Inc.	MFP-051	K123631	07/23/2013

4. Description of Device:

MSN-006 is a dual-cured, temporary crown and bridge resin. The components consists of Paste A and B, which are filled in a cartridge. Both pastes are automixed with a mixing tip.

5. Indications for Use:

1. Fabrication of temporary crowns, bridges, inlays, onlays and veneers
2. Fabrication of long-term temporary restorations

6. Technological characteristics:

The technical characteristics are similar (material formulation) but not the same as the predicate devices (Section 10). MSN-006 as compared to Protemp Plus and Luxatemp are two component systems based on resin/composite technology. Bench top testing indicates that even with different formulas, applicant device and predicate devices previously mentioned, meet specifications listed in ISO 10477 (Section 18).

7. Substantial equivalence:

The applicant device complies with all the requirements of ISO 10477: 2004 (Dentistry - Polymer-based crown and bridge materials).

The curing mechanism of the new and predicate devices is substantially equivalent in principle. Therefore, the new and predicate devices are the same/similar in function, and similar in composition and intended use. This supports that the compatibility and safety of the applicant device are substantially equivalent to the predicate devices.

In summary, indications for previously mentioned predicate devices and applicant device are the same. Differences in bench top performance tests meet or exceed requirements as outlined in ISO 10477 (Section 18). Data was analyzed utilizing basic statics when comparing to ISO 10477 (Sections 12 and 18).

Differences

The following differences may be noted between the predicate devices and MSN-006:

- All products listed under “Performance Test Results” (Table 18) meet ISO 10477 and differences in Flexural Strength, Water Sorption and Solubility are noted.

8. Packaging

Refills:

1. EM Cartridge (L) 62.5g (50mL) (1), GC MIXING TIP II SSS (15)
2. EM Cartridge (S) 12.5g (10mL) (1), GC Automix Tip Regular (10)

Mixing tip package:

1. GC MIXING TIP II SSS (60)
2. GC Automix Tip Regular (20)

Dispenser package:

1. GC CARTRIDGE DISPENSER II (1)
2. GRADIA CORE DISPENSER GUN (1)

9. Shades

A1, A2, A3, A3.5, B1, B3 and BW

10. Shelf Life Evaluation and Storage Conditions:

- Shelf Life 2 years
- Store in a cool and dark place. 4-25°C (39.2 - 77.0°F)